

1653

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT

(Under 37 CFR 1.97(b) or 1.97(c))

Docket No. **#5**

14750

In Re Application Of: **Ronald Buelow, et al.**

MAR 29 2002

Serial No.
09/921,819

Filing Date
August 3, 2001

Examiner
Unassigned

Group Art Unit
1653

Title: **PRODUCTION OF HUMANIZED ANTIBODIES IN TRANSGENIC ANIMALS**

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Address to:
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37 CFR 1.97(b)

1. ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application; within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; or before the mailing date of a first Office Action on the merits, whichever event occurs last.

37 CFR 1.97(c)

2. ☐ The Information Disclosure Statement submitted herewith is being filed after three months of the filing of a national application, or the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; or after the mailing date of a first Office Action on the merits, whichever occurred last but before the mailing date of either:

1. a Final Action under 37 CFR 1.113, or
 2. a Notice of Allowance under 37 CFR 1.311,
- whichever occurs first.

Also submitted herewith is:

- ☐ a certification as specified in 37 CFR 1.97(e);

OR

- ☐ the fee set forth in 37 CFR 1.17(p) for submission of an Information Disclosure Statement under 37 CFR 1.97(c).

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(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))

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Signature of Person Mailing Correspondence

Michelle Mustafa

Typed or Printed Name of Person Mailing Correspondence

Dated: **March 25, 2002**

Edward W. Grolz, Reg. No. 33,705
SCULLY, SCOTT, MURPHY & PRESSER
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Garden City, NY 11530
(516) 742-4343

EWG:ahs

CC:

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENTS

Applicant(s): Ronald Buelow, et al.

Examiner: Unassigned

Serial No: 09/921,819

Art Unit: 1653

Filed: August 3, 2001

Docket: 1475

For: PRODUCTION OF HUMANIZED
ANTIBODIES IN TRANSGENIC ANIMALS

Dated: March 25, 2002

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Assistant Commissioner for Patents
United States Patent and Trademark Office
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

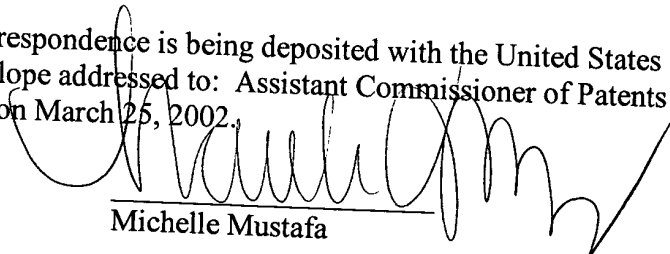
In accordance with 37 C.F.R. §§ 1.97 and 1.98, it is requested that the following references, which are also listed on the attached Form PTO-1449, be made of record in the above-identified case.

1. United States Patent No. 5,814,318, dated September 29, 1998, issued to Lonberg, et al.;
2. United States Patent No. 5,545,807, dated August 13 1996, issued to Surani, et al.;
3. United States Patent No. 5,570,429, dated October 29, 1996, issued to Paddock;

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner of Patents and Trademarks, Washington, D.C. 20231 on March 25, 2002.

Dated: March 25, 2002


Michelle Mustafa

4. United States Patent No. 5,416,260, dated May 16, 1995, issued to Koller et al.;
5. United States Patent No. 5,567,607, dated October 22, 1996, issued to Zhao, et al.;
6. United States Patent No. 5,453,357, dated September 26, 1995, issued to Hogan;
7. United States Patent No. 5,639,457, dated June 17, 1997, issued to Brem, et al.;
8. United States Patent No. 5,874,299, dated February 23, 1999, issued to Lonberg, et al.;
9. European Patent No. EP 0 438 474 B1, dated May 15, 1996, issued to Bruggemann, et al.;
10. International Publication No. WO 00/75300 A2, dated December 14, 2000, issued to Paul Ditullio, et al.;
11. Knight, et al., "Organization and Polymorphism of Rabbit Immunoglobulin Heavy Chain Genes", J. Immunol., pp. 1245-1250 (1985);
12. Huang and Stollar, "A Majority of Ig H Chain cDNA of Normal Human Adult Blood Lymphocytes Resembles cDNA for Fetal Ig and Natural Autoantibodies", The American Association of Immunology, Vol. 151, pp. 5290-5300 (1993);
13. Knight & Becker, "Molecular Basis of the Allelic Inheritance of Rabbit Immunology VH Allotypes: Implications for the Generation of Antibody Diversity", Cell, Vol. 60, pp. 963-970 (1990);
14. Pritsch, et al., "V Gene Usage by Seven Hybrids Derived From CD5⁺ B-Cell Chronic Lymphocytic Leukemia and Displaying Autoantibody Activity", Blood, Vol. 82, No. 10, pp. 3103-3112 (1993);
15. Lautner-Rieske, et al., "The Human Immunoglobulin χ Locus. Characterization of the Duplicated A Regions*", Eur. J. Immunol., Vol. 22, No. 4, pp. 1023-1029 (1992);
16. Lieberman, et al., "Structure of a Germline Rabbit Immunoglobulin V χ -Region Gene: Implications for Rabbit V χ -J χ Recombination", The Journal of Immunology, Vol. 133, No. 5, pp. 2753-2756 (1984);

17. Fan, et al., "Transgenic Rabbit Models for Biomedical Research: Current Status, Basic Methods and Future Perspectives", Pathology International, Vol. 49, No. 7, pp. 583-594 (1999);
18. Zhang, et al., "DNA Cloning By Homologous Recombination in Escherichia Coli", Nature Biotechnology, Vol. 18, No. 12, pp. 1314-1317 (2000);
19. Kametani, et al., "Comparative Studies on the Structure of the Light Chains of Human Immunoglobulins", J. Biochem., Vol. 93, No. 2, pp. 421-429 (1983);
20. McCormack, et al. "Chicken IgL Rearrangement Involves Deletion of a Circular Episome and Addition of Single Nonrandom Nucleotides to Both Coding Segments", Cell, Vol. 56, pp. 785-791 (1989);
21. Matthyssens and Rabbitts, "Structure and Arrangement of Human Heavy Chain Variable Region Genes", The Immune System, Vol. 1, pp. 132-138 (1981);
22. Etches, et al., "Strategies for the Production of Transgenic Chickens", Methods in Molecular Biology, Vol. 62, pp. 433-450;
23. Pain, et al., "Chicken Embryonic Stem Cells and Transgenic Strategies", Cells Tissues, Organs, Vol. 165, Nos. 3-4, pp. 212-219 (1999);
24. Sang, H., "Transgenic Chickens - Methods and Potential Applications", TIBTECH, Vol. 12, pp. 415-420 (1994);
25. Brem, et al., "YAC Transgenesis in Farm Animals: Rescue of Albinism in Rabbits", Molecular Reproduction & Development, Vol. 44, pp. 56-62 (1996);
26. Stice, et al., "Nuclear Reprogramming in Nuclear Transplant Rabbit Embryos", Biology of Reproduction, Vol. 39, pp. 657-664 (1988);
27. McCartney-Francis, et al., "Expression of K2 Isotype mRNA in Normal and Basilea Rabbits", Molecular Immunology, Vol. 24, No. 4, pp. 357-364 (1987);
28. Allegrucci, et al., "Preferential Rearrangement in Normal Rabbits of the 3' V_H Allotype Gene that is Deleted in Alicia Mutants...", Eur. J. Immunol., Vol. 21, pp. 411-417 (1991);
29. Frommel, et al, "Metabolism of γ G and γ M Immunoglobulins in Normal and Hypogammaglobulinemic Chickens", The Journal of Immunology, Vol. 105, No. 1, pp. 1-6 (1970);
30. Benedict, et al, "Inherited Immunodeficiency in Chickens: A Model for Common Variable Hypogammaglobulinemia in Man", Adv. Exp. Med. Biol., Vol. 88, No. 2, pp. 197-205 (1977);

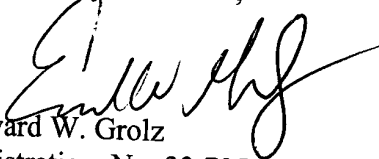
31. T. Wakayama, et al., "Full-Term Development of Mice from Enucleated Oocytes Injected with Cumulus Cell Nuclei", Nature, Vol. 394, pp. 369-374 (1998);
32. Cibelli, et al., "Transgenic Bovine Chimeric Offspring Produced from Somatic Cell-Derived Stem-Like Cells", Nature BioTechnology, Vol. 16, pp. 642-646 (1998);
33. Ishida, et al., "Production of a Diverse Repertoire of Human Antibodies in Genetically Engineered Mice", Microbiol. Immunol., Vol. 42, No. 3, pp. 143-150 (1998);
34. Tomizuka, et al., "Double Trans-Chromosomic Mice: Maintenance of Two Individual Human Chromosome Fragments Containing Ig Heavy and κ loci and Expression of Fully Human Antibodies", National Academy of Sciences, Vol. 97, Issue 2, pp. 722-727 (2000);
35. Sale, et al., "Ablation of XRCC2/3 Transforms Immunoglobulin V Gene Conversion into Somatic Hypermutation", Nature, Vol. 412 (2001);
36. Lanza, et al., "Extension of Cell Life-Span and Telomere Length in Animals Cloned from Senescent Somatic Cells", Science, Vol. 288, pp. 665-669 (2000);
37. Polejaeva, et al., "Cloned Pigs Produced by Nuclear Transfer from Adult Somatic Cells", Nature, Vol. 407, (2000);
38. K.J. McCreath, et al., "Production of Gene-Targeted Sheep by Nuclear Transfer from Cultured Somatic Cells", Nature, Vol. 405 (2000);
39. D. Bucchini, et al., "Rearrangement of a Chicken Immunoglobulin Gene Occurs in the Lymphoid Lineage of Transgenic Mice", Nature, Vol. 326, pp. 409-411 (1987);
40. Knight, et al., "Generating the Antibody Repertoire in Rabbit", Advances in Immunology, Vol. 56, pp. 179-218 (1994);
41. Langman, et al., "A Theory of the Ontogeny of the Chicken Humoral Immune System: The Consequences of Diversification by Gene Hyperconversion and its Extension to Rabbit", Res. Immunology, Vol. 144, pp. 422-446 (1993);
42. Campbell, et al., "Sheep Cloned by Nuclear Transfer from a Cultured Cell Line", Nature, Vol. 380, pp. 64-66 (1996);
43. Stice, et al., "Cloning: New Breakthroughs Leading to Commercial Opportunities", Theriogenology, Vol. 49, pp. 129-138 (1998);

44. Cibelli, et al., "Cloned Transgenic Calves Produced from Nonquiescent Fetal Fibroblasts", Science, Vol. 280, pp. 1256-1258 (1998);
45. Schnieke, et al., "Human Factor IX Transgenic Sheep Produced by Transfer of Nuclei from Transfected Fetal Fibroblasts", Science, Vol. 278, pp. 2130-2133 (1997).

Applicants are submitting copies of the above-cited references.

Inasmuch as this Information Disclosure Statement is being submitted in accordance with the schedule set out in 37 C.F.R. § 1.97(b), no statement or fee is required.

Respectfully submitted,



Edward W. Grolz
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Form PTO-1449 U.S. DEPARTMENT OF COMMERCE
(REV. 7-80) PATENT AND TRADEMARK OFFICE

Atty. Docket No.: 14750

Serial No.: 09/921,819

LIST OF PRIOR ART
CITED BY APPLICANT

(Use several sheets if necessary)

Applicants: Ronald Buelow, et al.

Filing Date: August 3, 2001

Group: 1653

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (if appropriate)
	AA	5,814,318	9/29/98	Lonberg, et al.			
	AB	5,545,807	8/13/96	Surani, et al.			
	AC	5,570,429	10/29/96	Paddock			
	AD	5,416,260	5/16/95	Koller et al.			
	AE	5,567,607	10/22/96	Zhao, et al.			
	AF	5,453,357	9/26/95	Hogan			
	AG	5,639,457	6/17/97	Brem, et al.			
	AH	5,874,299	2/23/99	Lonberg, et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	AI	EP 0438474B1	5/15/96	Europe				
	AJ	WO 00/75300A2	12/14/00	PCT				

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AK	Knight, et al., "Organization and Polymorphism of Rabbit Immunoglobulin Heavy Chain Genes", <u>J. Immunol.</u> , pp. 1245-1250 (1985)
	AL	Huang and Stollar, "A Majority of Ig H Chain Cdna of Normal Human Adult Blood Lymphocytes Resembles cDNA for Fetal Ig and Natural Autoantibodies", <u>The American Assoc. of Immunology</u> , Vol. 151, pp. 5290-5300 (1993)
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